REMARKS

Claims 35-39 and 53 stand rejected, and they have now been canceled and replaced with new claims 56-63. Support for these claims can be found in the as-filed claims and specification. Accordingly, these amendments introduce no new matter.

In view of the following amendment and response, the Applicants believe the claims presented herein are allowable. Reconsideration is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 35-39 and 53 were rejected under 35 U.S.C. §112, first paragraph. The Examiner states, *inter alia,*

> *....while being enabling for "an isolated polynucleotide encoding Neisseria meningitides LbpB selected from the group consisting of: SEQ ID NO:1 (nucleotide 100-nucleotide2274), SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, or SEQ ID NO:9' and for an isolated polynucleotide which encodes the amino acid sequence set forth in SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, or SEQ ID NO:10' and host cells and test kits comprising the polynucleotide sequences, does not reasonably provide enablement for "An isolated polynucleotide encoding a Neisseria polynucleotide sequence that is at least 90% identical to that of SEQ ID NO:1 (nucleotide 100-nucleotide2274), SEQ ID Nos: 3,5,7, or 9" nor is it enabled for methods of making a protein using these polynucleotides of for test kits for diagnosing neisserial bacteria in a human which comprise these polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.... Applicants have provided no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation the effects of different nucleotide substitutions and the nature and extent of the changes that can be made.*

As Applicants stated in response to the earlier office action, enablement requirement is still met even if a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. Applicants still maintain that Applicants provided enough guidance in the specification to enable one of ordinary skill how to determine, without undue experimentation, ways to retain the property of LbpB polypeptides. Once again, figure 9 of the application teaches that some amino acids are

conserved in all five sequences whereas other amino acid residues can be changed without affecting the activity of the LbpB. For instance amino acids 160-162 of the BNCV LbpB sequence could be changed from KWT to EWT or EQN without affecting the activity of the LbpB. Hence the skilled person can design polynucleotides encoding LbpB with sequences up to at least 90% identity from any of the specific disclosed sequences even with some level of experimentation. The specification supplies enough guidance with respect to the direction in which the experimentation should proceed.

However, for the sole purpose in expediting the prosecution of the case, Applicants have canceled and added claims to remove the "at least 90% identity" language. Applicants have canceled claims 35-39 and 53, and presented new claims 56-63. Claim 56 corresponds to canceled claim 53. Claim 57 is directed to polynucleotides which encode the polypeptide of SEQ ID NO: 2, 4, 6, 8 or 10 (i.e. degenerate codon sequences) which the Examiner deems allowable. Claim 58 is a new claim which finds its support in page 14, line 23-25. Other claims are directed to expression systems, host cells, a process for producing a polypeptide or cell, a kit for diagnosis which depend from claims 56, 57 or 58.

Applicants reserve the right to file continuation and/or divisional applications directed to the canceled subject matter in order to fully address the contested issues.

CLAIM REJECTION – 35 USC 112, First Paragraph

Claims 35-39 and 53 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states, *inter alia,*

> *The written description in this case only sets forth SEQ ID NO:1 (from nucleotide 100 to nucleotide 2274), 3,5,7 and 9 and equivalent degenerative codon sequences thereof, i.e., isolated polynucleotides encoding the amino acid sequence set forth in SEQ ID Nos: 2,4,6,8 or 10, and therefore the written description is not commensurate*

in scope with the claims which are broadly drawn to an isolated polynucleotide encoding N meningitides LbpB (claim 35) and polynucleotides which vary by 20% [sic] of the known sequences... With the exception of SEQ ID Nos:1(from nucleotide 100 to nucleotide 2274), 3,5,7 and 9 and the degenerates thereof, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Once again, Applicants respectfully disagree with the Examiner's contention. As stated previously, a skilled person can clearly understand what is meant by polynucleotides having at least 90% identity to SEQ ID NOs: 1, 3, 5, 7 or 9. Defining polynucleotides in terms of "identity" is describing sequences using a mathematical algorithm which is equivalent to precisely defining the DNA in terms of "structure, formula, chemical name, or physical properties" that the Reagent court required. The Examiner cites The Reagents of the University of California v. Eli Lilly for the proposition that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide adequate written description of the genus. However, the Reagents case can be clearly distinguished from the instant case because the Applicants are not defining the polynucleotides in terms of functional activity but in terms of "identity."

The Examiner states no disclosure beyond the mere mention of allelic variants is made in the specification. It is respectfully submitted that the allegation made by the Examiner is erroneous. For the record, what are listed in figure 9 are not simple allelic variants, but LpbB polypeptides from different species.

However, as stated previously, for the sole purpose in expediting the prosecution of the case, Applicants have canceled and added claims to remove the "at least 90% identity" language. Applicants reserve the right to file continuation and/or divisional applications directed to the canceled subject matter in order to fully address the contested issues.

Applicants believe that Applicants have now placed the application in condition of allowance. Accordingly, favorable reconsideration and allowance of the pending claims are earnestly solicited. If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney.

Respectfully submitted,

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